

### **REMARKS**

Applicants' Amendment is presented to support the RCE submitted herewith, and to respond to the September 5, 2007, Advisory Action (AA). The September 5 AA maintains the final rejections set forth in the final Office Action mailed from the US Patent Office on April 26, 2007, in response to applicant's August 27, 2007 Amendment After Final. A Petition For Extension of Time accompanies this PA with RCE, which extends the time for applicants response three (3) months, up to and including October 26, 2007.

The Amendment adds new independent claim 9, cancels claims 1-3 and 6-8 and 8 without prejudice or disclaimer of subject matter, and amends the dependency of claims 4 and 5 to depend from new independent claim 9, instead of from independent claim 1 (the dependency at filing). Claims 4, 5 and 9 are pending hereafter, where claim 9 is the independent claim. No new matter is added by the claims amendments, or by addition of claim 9.

Applicants' ultrasonic probe is designed and intended for use with an endoscope, by operation in which the ultrasonic probe is inserted into the body cavity. The probe includes an ultrasonic transducer, which includes a backing member. The backing member is included to attenuate ultrasonic waves that are generated at a frequency of about 5MHz by a piezoelectric element comprising the ultrasonic transducer. The ultrasonic transducer is immersed in an aqueous solution. Immersion in an aqueous solution presents an inherent problem for a backing member material. That is, the ultrasonic transducer, and therefore the ultrasonic probe, are designed to operate where the backing member displays an acoustic impedance in a fixed, predetermined range in the aqueous solution, and not absorb too much or too little of the aqueous solution. But in addition to being immersed in the aqueous solution during active operation, the probe including transducer and backing member are placed in close contact with the moistened

body wall in order to obtain ultrasonic tomographic images. Hence the vibration damping material that forms the ultrasonic probe for an endoscope is exposed to the moisture and/or aqueous solution during observing operation within the body cavity. Moreover, the endoscope is generally repeatedly used, and at such using, exposed or subjected to washing and sterilization. Thus, chemical agents or heat to which the ultrasonic probe with endoscope must necessarily be applied is also to the vibration-damping material.

The vibration-damping material must by its nature maintain a highly stable shape to prevent it from being deformed under the above-mentioned conditions. Over short or long-term use, the backing member shape must be maintained with minimal deformity so that the characteristics of the ultrasonic waves generated and received by the ultrasonic transducer do not unacceptably vary by the swelling or deforming thereof, due to the exposure to the moisture or aqueous solution, or deform thereof due to the exposure to the heat or chemical fluids used for cleaning and sterilization after or before use as already mentioned. If such swelling or deforming conditions occur during operation, the intended performance of the ultrasonic probe for an endoscope as designed cannot be realized.

The longevity or ability to repeatedly use the ultrasonic probe for an endoscope without the claimed vibration-damping material is not possible. Put another way, the vibration-damping material that comprises the ultrasonic transducer must be water-resistive, chemical agent and/or heat resistive and mechanically strong in light of the above-mentioned conditions. Hence, the inventors had, after various attempts to prepare a water-resistive, chemical agent and/or heat resistive and mechanically strong vibration damping member, concluded that a mixture comprising acrylonitrile-butadiene rubber (NBR), ethylene-propylene terpolymer (EPDM), and at least inorganic fine powders (recited by the language of new independent claim 9) is the most

suitable material for realizing water-resistive, chemical and/or heat resistive qualities required to maintain the probe vibration-damping characteristics during intended endoscopic operation.

In the September 5 AA, the Examiner responds to applicants' argument in the August 26, 2007, Amendment After Final, with respect to rejected claims 1, 2 and 3 (now cancelled). That is, the Examiner states that the hardness property of 80 –100 degrees in the A scale in conformity with JISK6253, and the ultrasonic absorbing coefficient of 10dB/mm or more at a frequency of 5 MHz, is obvious in view of US Patent No. 5,176,140 to Kami, in combination with US Patent No. 5,722,644 to Kinoshita. The Examiner supports maintaining the final rejections by asserting that it would have been obvious to discover optimum or workable ranges purportedly disclosed by Kinoshita's backing member by routine experimentation, citing In re Aller, 105 USPQ 233 (CCPA 1955), to support the final rejections (of cancelled claims 1, 2 and 3).

While claims 1-3 are cancelled, the subject matter of those cancelled claims is incorporated into newly presented independent claim 9. With respect to independent claim 9, applicants cannot agree with the Examiner's characterization of the instant facts with the law of Aller, which stands for "optimization" of ranges. In Aller, the Appellant's claimed process on appeal was found to be identical with a sulphuric acid-based process of the prior art except for being implemented in a higher temperature range. The Aller opinion states that where the general conditions of a claim are disclosed in the prior art such as in Appellant's preferred temperature range at issue in Aller, it is not inventive to discover such optimum or workable ranges by routine experimentation. Aller at 235. The general conditions of claim 9 are not found in Kinoshita. The use of Kinoshita as the secondary reference under Section 103(a) is distinguishable from the facts of Aller. There is no range, or optimized range taught by Kinoshita, taking the instant facts from within the precedential control of Aller.

Determining optimum or workable ranges for a backing member comprising an ultrasound probe that is inserted into a human body, and vibrating at 5 MHz is not a simple matter. A backing member constructed into the ultrasonic transducer for insertion into a human body during a medical procedure must not only work well in the miniaturized size required, but must also pass muster with governmental agencies that maintain the specifications for medical devices, as described in detail above. The design of applicants' invention as set forth in newly presented claim 9 was not a trivial task; the details of the design could not be readily gleaned by review or knowledge of Kinoshita, whether in combination with Kami, or alone. The instant invention was derived as a result of many experiments, repeated many times in an effort to realize the critical ranges as claimed, not routine experimentation. The claim 9 invention could not be obtained by "routine experimentation" in view of the combination of Kami and Kinoshita.

The only critical process identified in association with the Aller precedent as applied to Kinoshita is found in Kinoshita's at col. 2, lines 18-21, where they state that the resulting compounded composition is not restricted as long as it satisfies the specific gravity range of 1.6-2.8 as well as adhesive strength range of 0.5-2.0 Kg/25 mm below. These ranges or features are not included in applicants' claim 9 (nor claims 4 and 5). Nor does Kinoshita make mention of preparing a compound to meet a hardness property in any "range" of degrees in the A scale, still less a hardness property in a "range" of 80 –100 degrees in the A scale in conformity with JISK6253 in conformity with JISK6253, and the ultrasonic absorbing coefficient of 10dB/mm or more at a frequency of 5 MHz and the absorption and acoustic impedance range of 100,000 to 800,000 kg/(m<sup>2</sup>s), required by the invention as set forth in new claim 9.

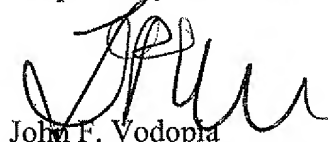
With all due respect, the Examiner misapplies Aller to the instant facts when he asserts that the general conditions at issue in Aller are met by Applicants' rejected claims (new claim 9,

because Kinoshita discloses a list of compounds, several of which being constituent parts of the claimed backing member. Applicants do not agree with the Examiner's stated position that merely naming the claimed constituent compounds by Kinoshita (the general condition) renders the claimed constituent compositions, and the claimed ranges of operation of a backing member manufactured in accord with the limitations, or that it would have been obvious to discover the optimum or workable ranges by routine experimentation, as per the Aller holding. Kami and Kinoshita combined do not teach or suggest a limitation that when immersed in an acoustic medium, the backing member displays an absorption in a range of 2.5 % or less, and displays and acoustic impedance in a range of  $(1-8) \times 10^6 \text{ kg/(m}^2\text{s)}$ .

Claims 4 and 5 as amended now depend from new claim 9. New claim 9 includes each of the limitations of applicants' cancelled claims 1, 2, 3 and 6. Because claims 4 and 5 depend from claim 9, claims 4, 5, and 9 are patentable in view of Kami and Kinoshita, and over Kami, Kinoshita, Erikson and Dam, for at least the reasons stated. Hence, applicants respectfully request the withdrawal of the rejection of claims 4 and 5 under Section 103(a) in view of any combination of the four (4) references, and allowance of claims 4, 5 and 9.

If the Examiner believes that a telephone conference with applicants' attorneys would be advantageous to the disposition of this case, the Examiner is asked to telephone the undersigned.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John F. Vodopla", written over the printed name.

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